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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,930	11/16/2001	Thomas P. Jerussi	4821-438-999	7891

20582 7590 10/10/2008

JONES DAY
222 East 41st Street
New York, NY 10017-6702

EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/987,930	JERUSSI ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,61-68,70-73,75-77 and 79* is/are pending in the application.

4a) Of the above claim(s) *68,71-73,75,77 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,61-67,70 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 07/02/2008.

- Claims 13, 61-67 and 76 have been amended.
- Claims 13, 61-68, 70-73, 75-77 and 79 are pending in the instant application.
- Claims 68, 71-73, 75, 77 and 79 have been previously withdrawn from consideration.

Claim Rejections - 35 USC § 112

Claims 13 and 61-67 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **are withdrawn** in view of Applicant's Amendment.

Claim Rejections - 35 USC § 102

Claims 13, 61-67, 70, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by MORGAN et al (US 6,274,579) **are withdrawn** in view of Applicant's Amendment.

Claim Rejections - 35 USC § 103

Claims 13, 61-67, 70, and 76 rejected under 35 U.S.C. 103(a) as being unpatentable over MORGAN (US 6,274,579) in view of GLENBERG et al (Report on efficacy of treatments for bipolar disorder. Psychopharmacol Bull. 1993;29(4):447-56) **are maintained** for reasons of record in the previous office action filed on 03/05/2008.

Applicant argues that although MORGAN reports that the anti-depression activity of racemic bupropion is likely to result from (S,S)-hydroxybupropion, it does not provide any disclosure or suggestion that bupropion may be replaced with (S,S)-hydroxybupropion in any and all methods where bupropion is used. The Examiner finds this argument unpersuasive, because it would have be obvious for the person of ordinary skill in the art to replace bupropion with (S,S)-hydroxybupropion when MORGAN disclosed the activity resides in the (S,S)-hydroxybupropion metabolite (see col. 2, line 16-20).

Applicant argues that MORGAN discloses that , while (S,S)-hydroxybupropion "was approximately twice as potent as [racemic bupropion] as an NA inhibitor," it was "approximately 10-fold less potent as an inhibitor of dopamine uptake." Therefore, at most, MORGAN merely shows that (S,S)-hydroxybupropion has different, but not necessarily more desirable, pharmacological properties than racemic bupropion. The Examiner finds this argument unpersuasive, because MORGAN disclosed that "behavioral and electrophysiological data suggest that the effects of Wellbutrin [racemic bupropion] are mediated by a noradrenergic [NA inhibitor] mechanism (see col. 7, line 34-37); thus, MORGAN is not disclosing that (S,S)-hydroxybupropion is different from racemic bupropion, but that (S,S)-hydroxybupropion is more potent for behavioral function than racemic bupropion, because (S,S)-hydroxybupropion, the metabolite of racemic bupropion, is where the activity reside for behavior functions, such as mania and bipolar disorder.

Applicant argues that MORGAN clearly discloses that "the mechanism of action of bupropion, as with other antidepressants, is unknown"; thus, MORGAN certainly would not have taught or suggested to those skilled in the art a reason that (S,S)-hydroxybupropion can replace bupropion in all of the uses contemplated for bupropion. The Examiner finds this argument unpersuasive, because although "the mechanism of action of bupropion, as with other antidepressants, is unknown", does not mean that bupropion would not be used to treat anything. In fact, bupropion is well known to be used for a variety of cerebral function ailments. Thus, it would have be obvious for the person of ordinary skill in the art to replace bupropion with (S,S)-hydroxybupropion when MORGAN disclosed the activity resides in the (S,S)-hydroxybupropion metabolite (see col. 2, line 16-20).

Applicant argues that GELENBERG does not provide anything regarding the desirability of singling out bupropion from the long list of disclosed agents. The Examiner finds this argument unpersuasive, because GELENBERG disclosed "bupropion may be better than other second-generation heterocyclic antidepressants..." (see pg. 451, 1st column); thus, GELENBERG does provide the desirability of singling out bupropion from a list of disclosed agents.

Applicant argues that GELENBERG actually teaches away from using bupropion. The Examiner finds this argument unpersuasive, because Applicant fails to elaborate on how GELENBERG actually teaches away from using bupropion.

Applicant argues that a study found "ECT to be superior to the other four treatments: overall efficacy rates were approximately 79 percent for ECT...," clearly

indicating that ECT was deemed a better alternative to other compounds tested, including antidepressant. The Examiner finds this argument unpersuasive, because the study compared ECT with tricyclic antidepressant, not a second-generation antidepressant, such as bupropion. Additionally, there were ECT biases in the study, since patients selected in this study had not responded satisfactorily to previous trials with antidepressants. Furthermore, other ECT studies failed to find any differences (see pg. 451, 1st column) between ECT and antidepressants.

Applicant argues that MORGAN itself discloses that the pharmacological effects of bupropion and (S,S)-hydroxybupropion are different (see pg. 10, above); thus the allegation made in the Office Action that "bupropion and its metabolites utilize the same pathways to obtain the same pharmacological effect" is incorrect. The Examiner finds this argument unpersuasive, because as discussed above, MORGAN disclosed that "behavioral and electrophysiological data suggest that the effects of Wellbutrin [racemic bupropion] are mediated by a noradrenergic [NA inhibitor] mechanism (see col. 7, line 34-37); thus, MORGAN is not disclosing that (S,S)-hydroxybupropion is different from racemic bupropion, but that (S,S)-hydroxybupropion is more potent for behavioral function by the noradrenergic mechanism than racemic bupropion, because the activity for behavior functions, such as mania and bipolar disorder, resides in the (S,S)-hydroxybupropion, which is a metabolite of racemic bupropion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jake M. Vu, PharmD, JD
Art Unit 1618

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/987,930	JERUSSI ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	